Immunocept, LLC, et al v. Fulbright & Jaworski Doc. 4

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

FILED
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CLERK, U.S. DISTRICT COURT
WESTERN DISTRICT OF TEXAS
BY ______ DEPUTY CLERK

IMMUNOCEPT, LLC, PATRICE ANNE LEE, AND JAMES REESE MATSON	§	
	§	
Plaintiffs,	§	
	§	
v.	§	CAUSE NO. A050A334 SS
	§	
FULBRIGHT & JAWORSKI, LLP,	§	
	§	
Defendant.	§	

DEFENDANT FULBRIGHT & JAWORSKI, LLP'S MOTION TO EXCLUDE MARTHA FELDMAN'S TESTIMONY

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COMES NOW, Fulbright & Jaworski, LLP ("Fulbright"), and files this Motion to Exclude the Testimony of Martha Feldman, and in support thereof, would respectfully show the Court as follows:

I. INTRODUCTION

In the words of Plaintiffs' liability expert, a patent "only gives the right to exclude others, it doesn't give the right to do." **Exhibit B** (Depo. of A. MacPherson at 161).[1] It follows then, that a patent is only valuable to the holder when accompanied by the "right to do" the idea that the patent covers. This "right to do" represents a central and fatal gap in Plaintiffs' evidence. Specifically, the Plaintiffs' claims in this case and the success of their proposed LPHF method covered by the '418 patent hinge on whether the FDA will ever approve the LPHF method for treatment of sepsis. Without FDA approval, Plaintiffs cannot test or sell the LPHF to treat humans with sepsis. Plaintiffs have not even begun—nor are they ready to begin—the process of applying for FDA's rigorous "Class III Premarket Approval." Accordingly, Plaintiffs have no ***evidence*** that they would receive FDA approval to test humans with their LPHF method, or that the FDA would approve their "large pore hemofiltration" method for treatment of sepsis. Because they have no ***evidence***, they have retained Martha Feldman as an "expert" to foretell and prophesy what the FDA "will do" with regard to the LPHF. Plaintiffs should not be allowed to bridge this wide gap in proof with the wildly speculative testimony of Martha Feldman about what the FDA will do or would do with respect to the Plaintiffs' LPHF method.

A. Opinions Subject to Exclusion under *Daubert*

Ms. Feldman offers the following speculative and conclusory opinions about what the FDA "will" do with respect to the LPHF:

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[1] **Exhibit A** to the Appendix is an affidavit that authenticates the other exhibits that support this motion.

- "the FDA will approve Immunocept's IDE and Immunocept will be able to conduct clinical trials."
- "I also believe that this device will obtain FDA approval for the treatment of sepsis and septic shock."

Exhibit C (Feldman Expert Report, ¶¶14, 15). Each of these opinions should be excluded under the requirements of FED. R. EVID. 702; *see also Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 591-93 (1993). Ms. Feldman offers these opinions despite the fact that Plaintiffs have not yet:

- Completed the necessary "preclinical" testing of the LPHF to demonstrate that it is safe to test the LPHF on humans;
- Completed the necessary "dose finding" study that would determine how the LPHF would be tested on humans in a clinical trial;
- Begun the process of applying to the FDA for permission to test the LPHF method on humans in a pivotal clinical trial;
- Obtained permission from the FDA to conduct clinical trial studies using the LPHF method on humans with sepsis;
- Conducted any clinical trials on humans to determine whether the device is safe or effective;
- Generated the "valid scientific evidence of safety and efficacy" necessary to obtain FDA approval of a Class III high risk device such as the LPHF.

These steps are Herculean hurdles to any inventor seeking to ultimately market a significant risk product. Yet Ms. Feldman assumes away the critical issue of whether Plaintiffs could successfully high jump these hurdles in order to reach the conclusion that the FDA will approve" the LPHF. No expert can make such an analytical leap; Ms. Feldman should not be allowed to try.

II. BACKGROUND OF THE FDA APPROVAL PROCESS

To understand the leap Feldman makes, it is helpful to first understand the FDA approval process. There are several different "paths" for a device to obtain final FDA approval. It is undisputed that the Plaintiffs' LPHF device would have to take the most rigorous and onerous path—the "Class III" path, which is reserved for "high risk devices" that present a potential for serious risk to the health, safety or welfare of the subject. *Id.* at ¶9; **Exhibit D** (Depo. of M. Feldman at 57, 86-87; 200); *see* 21 C.F.R. 812.3(m)(1). Class III devices have the highest FDA burden because they pose the highest risk for their intended use. **Exhibit D** at 250-51.

Ms. Feldman is an employee of a "regulatory, clinical and quality assurance consulting firm." *Id.* at 8. She is *not* an expert in the subject matter or the underlying science of any invention that she helps shepherd through the FDA process; she merely is knowledgeable about designing clinical trials and how the process works. The process for seeking FDA approval of a Class III "high risk" device entails several stages:

First, an applicant must test the device using nonclinical (bench) and preclinical (animal) studies and show "that the results indicate that it is safe to proceed with the human testing." **Exhibit C**, ¶11).

Second, only if the applicant can show nonclinical and preclinical studies that demonstrate that it is safe to proceed with human testing, then the applicant applies to the FDA for an Investigational Device Exemption ("IDE"). There, a team of people at the FDA must review the quantity and quality of the submitted prior studies and submit their opinions to the Consumer Safety Office, which makes the decision whether or not to grant an IDE. **Exhibit D** at 54. If granted, an IDE then allows the applicant to proceed to clinical trials using human subjects. *Id.* at 52-53.

Third, if the applicant obtains an IDE, then the applicant (Immunocept) would have to undergo at least two levels of clinical trials. *Id.* at 119. The first is a "dose-finding study" to determine the optimal dose and other measurements to use in the next trial. The second is a "pivotal clinical trial" to determine the impact of the device on humans. The pivotal clinical trial is "the most intensive, rigorous trial that would be required in order to get a Premarket Approval Application ("PMA")." *Id.* at 118. The pivotal clinical trial is the study "upon which a PMA is going to rise or fall for this device." *Id.* at 122. The purpose of these clinical trials is to get "valid scientific evidence" of the safety and effectiveness of the device in order to apply for a PMA.

Fourth, the applicant applies to the FDA for a PMA. There, the FDA puts together a statistician and a consumer safety officer and different consultants and medical officers within the FDA, as well as the FDA Advisory Panel to review the clinical trial data. *Id.* at 149. The panel makes a recommendation to the FDA, and the FDA makes an independent decision about whether or not to grant a PMA. *Id.* at 150.

Finally, if the applicant has statistical support showing the product is safe and effective for its intended use, the applicant would be ready to apply for FDA approval.

Plaintiffs' LPHF filter is in the ***first stage*** of this process. Plaintiffs have not yet had any initial meetings with the FDA, **Exhibit E** (Depo. of P. Lee at 203), nor have they applied for an IDE. **Exhibit D** at 55. They therefore do not even have *permission* to test their filter on human subjects. They have not yet conducted dose-finding studies or planned a pivotal clinical trial. They therefore have no evidence of the effect or safety of the filter on humans. Yet Plaintiffs would have Feldman testify before the jury that, after a few discussions with Plaintiffs about their subjective beliefs regarding the LPHF method, she may testify as an "expert" that their filter will clear every one of these stages and that it "will obtain FDA approval." **Exhibit C** at ¶15. Federal law does not permit such speculative "expert" testimony.

III. APPLICABLE LAW

Federal Rule of Evidence 702 determines the admissibility of all expert testimony, and places the qualifications of the witness, the sufficiency of his data, the reliability of his methodology, and the "fit" of that methodology to the facts squarely at issue. FED. R. EVID. 702; *see also Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 591-93 (1993). The Plaintiffs bear the burden of proving that Feldman's testimony meets the standards of Rules 702 and 703. *See, e.g., United States v. Fullwood*, 342 F.3d 409, 412 (5th Cir. 2003).

The "gatekeeping" obligation assigned to trial judges by *Daubert* applies to non-scientific expert testimony. *Kumho Tire Co. Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). Although Feldman's opinion is not readily susceptible to *Daubert* analysis, as it is based solely on her experience and cannot be tested, or verified, or subjected to peer review, the Court should find her conclusion is not sufficiently reliable to "assist the trier of fact to understand the evidence or to determine a fact in issue," FED. R. EVID. 702, and that in any event its value is substantially outweighed by the danger of unfair prejudice or misleading the jury. FED R. EVID. 403.

IV. ARGUMENT AND AUTHORITIES

Feldman's expertise is limited to the FDA *process*, and that is where her testimony should end. Feldman may be able to tell the jury what the steps are for FDA approval, but—as she conceded in various ways throughout her deposition—any conclusion about FDA approval would be based on nothing more than assumptions about results of hypothetical preclinical studies (which she did not even look at) and hypothetical clinical studies (which have not even been approved to begin). As she confessed several times throughout her deposition, "I do not have a crystal ball." **Exhibit D** at 213, 292; *see also* 214 ("I have the opinion that this product will get through. But there is no way I can know it. Nobody can guarantee something down the road.").

When an expert "brings to court little more than his credentials and a subjective opinion," this is not evidence that would support a judgment." *Viterbo v. Dow Chem. Co.*, 826 F.2d 420, 421-22 (5th Cir. 1987). Here, Plaintiffs seek to take an expert on the procedural aspects of the FDA approval process and ask her to assume away the gaps in their evidence, so that she may conclude that their invention would prove safe and effective and would therefore receive FDA approval. This is nothing more than a credentialed person making a subjective opinion, and it is patently unscientific and devoid of methodology.

A. Feldman's opinions are based on a series of unfounded assumptions.

First, consider the assumptions that Feldman made to entertain the quantum leap to final FDA approval:

1. Feldman has not considered the sufficiency of the preclinical tests.

Feldman did not analyze the preclinical testing to determine whether it would be sufficient to get an IDE to even test the LPHF on humans. *Id.* at 72. She is not offering any opinions on whether Plaintiffs' animal studies are sufficient, *id.* at 64-65, and she would not know whether any additional preclinical studies need to be done in order to get an IDE. *Id.* at 66.

She is merely accepting Plaintiffs' subjective opinion that they have done everything necessary to proceed with an IDE application. *Id.* at 45. But Plaintiffs are in no position to feed Feldman the hypothesis that they are ready to proceed with an IDE, because they have not even had an initial meeting with the FDA to determine what the FDA might demand. **Exhibit E**, at 203. They presently have none of the insight that might come from an initial meeting with the

FDA:

> Q: [I]f I'm sitting here today, it's hard to predict what the FDA might demand as far as clinically significant results in a pivotal clinical trial of this filter?
> A: Yes. That's why you have the pre-IDE meetings with them so you come to agreement before you even start the study.

Exhibit D at 177. It is not surprising then that Feldman concedes that she is speculating about how an application for an IDE would turn out. *Id.* at 71.

Even if Feldman were a sepsis expert and had reviewed the preclinical studies thoroughly, she would still be left to speculate whether Plaintiffs' studies to date would be sufficient to satisfy the FDA. This is because the IDE process is truly a black box. Feldman admits, "I can only speak to my experience because all IDE information is confidential by the FDA and there is no way could find out or any public person could find out whether or not IDEs were rejected or not and for what reason. That's not publicly available." *Id.* at 68. Feldman could not even tell the jury what *percentage* of devices are approved for an IDE—that, too, is confidential. *Id.* at 76. No one should be allowed to testify about what a governmental body *will* decide—particularly when its decision-making is clothed in confidentiality.

2. *Feldman is assuming that hypothetical clinical trials on humans would prove successful.*

Although Feldman testified that the Class III rigorous pivotal clinical trial is the study "upon which a PMA is going to rise or fall for this device," *id.* at 122, she candidly admits that she cannot know what the results of that trial would be:

> Q. Now, all of that valid scientific evidence of safety and efficacy for this filter is yet to be generated in the future, right?
> A. Correct.
> Q. And would only be generated through a pivotal clinical trial?
> A. That's correct.
> Q. Which has not happened?
> A. Correct.
> Q. And therefore you don't have any valid scientific evidence of safety or

effectiveness to look at with respect to this filter –
A. Correct.

Id. at 162.

Q. You do not have a valid scientific evidence of safety or effectiveness for the Immunocept filter to look at in forming your opinions in this case, correct?
A. That's correct, because there is no information.

Id. at 164.

Q. So of the things that you would want to look at in assessing the likelihood of this filter getting a PMA is the extent to which valid scientific evidence that the FDA would look at already exists, right?
A. Right.
Q. And it doesn't, right?
A. Uh-huh.
Q. **And so that relevant factor you couldn't go and look at in formulating your opinions, right?**
A. Right.
Q. And that's, in fact, going to be the most important factor in whether this device would get a PMA?
A. Correct.
Q. Far more important than the anecdotal papers, animal studies or subjective beliefs of the inventors?
A. That's correct.

Id. at 175-76.

Q: And you haven't looked at any studies, as I understand it, on humans that lead you to believe one way or the other whether this device will prove effective?
A: They didn't ask me to look at anything like that.

Id. at 173.

Feldman admits that the FDA does not consider subjective beliefs of the inventors of a device and the FDA Panel makes decisions based solely on "valid scientific evidence" of safety and efficacy generated in a pivotal clinical trial. Yet in conducting her analysis and reaching her speculative conclusion that the LPHF "will be approved," Feldman has only considered and assumed wholesale the subjective beliefs of the inventors—the Plaintiffs—and not any valid scientific evidence. Feldman's opinions about the "most important factor in whether the device would get a PMA" are nothing more than a wholesale adoption of Plaintiffs' opinions:

Q. You have not made any independent analysis or study of the likelihood that the hemofilter will prove safe and efficacious?
A. That's right.
Q. You don't even have that expertise, do you?
A. That's right.
Q. Okay. And so you are relying completely upon Dr. Bellomo's report and your conversation with Dr. Matson for an understanding about the likelihood of the filter being safe and effective?
A. Correct.
Q. You are just accepting that wholesale as an input into your analysis?
A. Yes, because that's how my practice usually goes.

Id. at 280.

Feldman's conclusion that the FDA will approve Plaintiffs' device is therefore tautological. She concludes that the device will obtain FDA approval ***if*** what Plaintiffs have told her is true regarding safety and efficacy:

Q. So it's your testimony that there is no chance that this device will not obtain FDA approval?
A. I believe that's true if all of the assumptions given to me were correct. And those are the things that I didn't read and I have no knowledge of. But if the assumptions that I was presented with the day I started, I think that this statement is true.

Id. at 210. But if Plaintiffs are wrong, that would affect her conclusions:

Q. Okay. And in this instance though – well, first of all, have you ever dealt with a medical device for treating sepsis in an IDE context?
A. No.
Q. And have you ever submitted an IDE without any bench or preclinical testing that demonstrates the device will be safe enough to test on humans?
A. No.
Q. That would be fatal to an IDE, right?
A. Right.
Q. But you are not – you haven't really looked in detail at whether Immunocept has at this point in time done the preclinical testing sufficient to make a showing about whether it will be safe enough to test in humans?
A. That's right. I haven't.

Q. But if they haven't, then they won't be able to get an IDE?
A. That's right.
Q. If they don't get an IDE, they can't do clinical trials?
A. Correct.
Q. If they don't do clinical trials, they won't get a PMA?
A. Right.
Q. And so you have concluded in this case that you believe they will get a PMA, right?
A. Yes.
Q. That's one of your opinions?
A. Yes, it is.
Q. We'll talk about that a little bit later. But if, in fact, it's the case that they have not done the necessary preclinical testing to get an IDE, then that would affect your conclusion, right?
A. Yes.

Id. at 68-69.

Feldman's testimony boils down then to the rather obvious point that either the device would or would not obtain FDA approval, depending on whether the FDA allows clinical testing and then depending on the results of those tests. The jury needs no "expert" assistance with such a pedestrian concept.

B. Feldman's "methodology" is simply non-scientific guesswork.

Feldman testified that her "methodology" is nothing more than her years of experience. *Id.* at 211-12. She concedes that it is not "scientific," and that, without the valid scientific data of safety and efficacy, ***no one*** is qualified to say that the device will be approved:

Q. And so you really didn't employ any kind of scientific methodology to come up with your conclusion in Paragraph 15 that the device will obtain FDA approval, right?
A. That's correct.
Q. And you will agree with me that there is a big difference between saying, "I know how to design clinical trials and I can design a clinical trial" and saying, with a crystal ball, "This will result in valid evidence of safety and efficacy sufficient to get a PMA," right?
A. That's right.
Q. And while you may be qualified, based on your years of experience, to design a clinical trial or put together what you did in Exhibit B, a does-finding clinical study protocol, **you are not qualified and I'm not**

qualified and nobody is qualified to say that a clinical pivotal trial will result in scientific evidence of safety and efficacy sufficient to get a PMA approval, right?

A. That's right.

Q. And unless you have the valid scientific data of safety and efficacy of this filter, no one is qualified to say that the device will be approved?

A. That's right.

Id. at 215-16 (emphasis added).[2]

According to the Advisory Committee Notes accompanying the 2000 Amendments to Rule 702:

> If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it." [ ] The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable.

FED. R. EVID. 702 advisory committee's note. Feldman offers nothing—other than the Plaintiffs' subjective beliefs—to tie her experience to her ultimate conclusion. Finally, she admits that she does not have a crystal ball:

Q. But all of that experience doesn't bear upon the crucial issue of whether this particular device will prove safe and effective through valid scientific evidence?

A. That's correct. Nobody could know that now.

Q. Right. You don't know that now?

A. No, but this was my opinion that it's likely that it would get through, it will get through.

Q. Right. But your opinion – you have given your opinion. At the same time, you don't know whether the testing in a pivotal clinical trial will produce valid scientific evidence of safety and efficacy for this product?

A. Nobody does.

Q. And you don't?

A. I don't have a crystal ball.

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[2] This concession accords with Plaintiffs' damages expert, James Malakowski, who has also said that no one could know whether the FDA would approve the device:

> Because ***the product embodying the Patent is not yet fully tested*** (i.e., the ***necessary clinical [human] trials have not been conducted***), ***it is not known with certainty*** whether the product will successfully complete the FDA approval process and perform consistent with expectations.

See **Exhibit F** at 37 (emphasis added).

Id. at 213.

As a result, Ms. Feldman's opinions are simply speculation and guesswork without valid scientific methodology and evidence. *See, e.g.*, *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d 839, 852 (N.Y. App. Div. 2003) ("No expert could honestly opine that [FDA] approval would have been granted without engaging in rank speculation. The approval process is accompanied by countless opportunities to decline or delay further progress."); *Twin Cities Bakery Workers Health and Welfare Fund v. Biovail Corp.*, 2005 WL 3675999, *4-5 (D. D.C. March 31, 2005) (slip op.) (excluding experts' opinions on "whether or not, and when, the Food and Drug Administration would have made complex, discretionary, multi-layered, case-specific decisions relating to the initial approval and subsequent need to recall a prescription drug," because "the experts' declarations are too speculative to forge the chain of causation plaintiffs' proof of damages requires").

V. CONCLUSION

Plaintiffs have hired Feldman to take their conclusory opinions as true and pile assumption upon assumption about the likelihood of successfully navigating a complex, expensive and exhaustive FDA approval process. Without a "crystal ball," Feldman concedes that neither she nor anyone else can predict whether the FDA would approve the Plaintiffs' LPHF method. Her unscientific guesses—based solely on subjective discussions with the self-interested Plaintiffs—about what a yet-to-be-identified panel of FDA experts and administrators might do in the future based on yet-to-be-generated clinical testing of the Plaintiffs' LPHF, constitute rank speculation, are not based on reliable scientific method, and will not assist the trier of fact. Accordingly, Fulbright respectfully submits that the Court should exclude Martha Feldman's testimony as discussed above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served as shown below on counsel of record on February 20, 2006.

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CERTIFICATE OF CONFERENCE

The undersigned hereby certifies that we have attempted to reach Plaintiffs counsel in an effort to resolve this dispute without court action. We were unable to do so, but based on the nature of the relief requested in this motion, we believe that Plaintiffs will be opposed to this Motion.

Connie H. Pfeiffer

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

Notice of Document/Attachment(s) Not Imaged but Stored with Document in Case File

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Civil Case No. A:05-CA-334 SS

Immunocept LLC et al.

VS.

Fulbright & Jaworski LLP

Attachments to Document #: 49

Description: Defendant Fulbright & Jaworski, LLP's Motion to Exclude Martha Feldman's Testimony

File Date: February 21, 2006

Prepared by: dm

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